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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,034	09/05/2003	James Hunter Boone	TLAB.100294	8482
5251	7590	05/17/2005	EXAMINER	
SHOOK, HARDY & BACON LLP 2555 GRAND BLVD KANSAS CITY,, MO 64108			VENC, DAVID J	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/656,034	Applicant(s) BOONE ET AL.	
	Examiner David J. Venci	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on February 14, 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 17-25 is/are pending in the application.
- 4a) Of the above claim(s) 4-5 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-14, 17, 18 and 20-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-14 and 17-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on September 5, 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/08/03; 07/06/04</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-14 and 17-25, in the reply filed on February 14, 2005, is acknowledged. In addition, Applicant's election without traverse of species A, Crohn's disease, readable on claims 1-3, 6-14, 17-18 and 20-25, is acknowledged.

Claims 4-5 and 19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species, there being no allowable generic or linking claim.

Currently, claims 1-3, 6-14, 17-18 and 20-25 are under examination.

Specification

The disclosure is objected to because of the following informalities:

In paragraph [0004], the patent number for U.S. Patent 6,218,120 appears incorrect (see U.S. Patent 6,218,129).

In paragraph [0015], the recitation of a "later flow" dipstick is indefinite. It is not clear what kind of dipstick is referenced.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 10-11, 13-14, 20 and 24-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 6, 10-11, 20 and 24, the recitation of "the endogenous anti-neutrophil cytoplasmic antibodies" lacks antecedent basis. The term "endogenous" is indefinite because the point of reference(s) defining the boundary between "endogenous" and "not endogenous" is/are not clear.

In claims 6 and 20, the recitation of "the total" lacks antecedent basis. The term "total" is indefinite because it is not clear whether/how the noun "antibodies" is modified by the adjective "total."

In claim 13, the recitation of "the antibodies" lacks antecedent basis and is indefinite because it is not clear whether "the antibodies" references "endogenous anti-neutrophil cytoplasmic antibodies" or "polyvalent antibodies to human immunoglobulin" or both.

In claims 14 and 25, the recitation of "the assay comprises one of..." and "the sample is one of..." is indefinite because it is not clear whether a Markush-type claim is intended.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 6-14, 17-18 and 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walsh & Rose (US 6,218,129) in view of Padron (US 5,359,038).

Walsh & Rose describe a method comprising the steps of: obtaining a sample (see col. 5, lines 7-8, "any biological specimen... that contains antibodies") from a person (see Table 1), and determining the presence of anti-neutrophil cytoplasmic antibodies (see Abstract, "determining... whether the sample is positive for anti-neutrophil cytoplasmic antibodies").

Walsh & Rose do not teach a method incorporating feces.

However, Padron teaches the use of feces for isolating antibodies used in diagnosis and treatment (see Abstract). Therefore, it would have been obvious for a person of ordinary skill in the art to modify the method of Walsh & Rose by using feces because Padron discovered a method capable of producing "in the order of hundreds of milligram" of immunoglobulin (see col. 2, lines 66+).

With respect to claims 2-3, 11-12 and 17-18, Walsh & Rose describe a method wherein a diagnosis of ulcerative colitis or Crohn's disease may be substantially concluded (see Example III, see col. 6, lines 53-59).

With respect to claims 7, 11 and 21, Walsh & Rose describe a method wherein samples are diluted (see col. 5, lines 17-18).

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With respect to claims 8, 11 and 22, Walsh & Rose describe a method further comprising the step of contacting the sample with neutrophil cytoplasmic antigens (see col. 4, lines 47+).

With respect to claims 9, 11 and 23, Walsh & Rose describe a method wherein polyvalent anti-human Ig antibodies are used (see col. 12, line 17).

With respect to claims 10-11 and 24, Walsh & Rose describe a method wherein OD₄₅₀ is used (see col. 12, lines 5-6).

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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David J Venci
Examiner
Art Unit 1641

djv



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05/13/05